

### Remarks

The amendment to the specification at the top of page 1, reciting the claim of priority does not add new matter and merely clarifies the relationship between the present application, “a 371 of PCT/US98/17769, filed 08/27/98,” and the parent application, USSN 08/920,630, from which priority was expressly claimed. [see Exhibit A: the official filing receipt.].

The Official Filing Receipt **incorrectly** states that the present application, which was granted a § 102(e) filing date of 08/20/01, was both:

“a 371 of PCT/US98/17769, filed 08/27/98,  
**and a CIP of USSN 08/920,630, filed 08/27/97, ABN”**

However, the Official Filing Receipt should recite as follows:

“a 371 of PCT/US98/17769, filed 08/27/98,  
**and which is a CIP of USSN 08/920,630, filed 08/27/97, ABN”**

Support for this amendment to the specification comes from the fact that the specification is now required to recite the claim of priority in the first paragraph, and present application is the 371 national phase of PCT/US98/17769, filed 08/27/98, utilizing the same specification, and claiming priority to the PCT application’s PCT filing date (08/27/98). In addition, on its face, the PCT application, PCT/US98/17769, claims priority from USSN 08/920,630, filed 08/27/97. [See Exhibit B: cover page of PCT/US98/17769.] Thus, it is clear that PCT/US98/17769 is claiming priority directly from USSN 08/920,630. Hence, the clarifying amendment is required under the rules and does not add new matter.

In addition, the declarations [Exhibit C] that were originally filed with this application expressly reflect that the present application recited that priority was from both PCT/US98/17769 and USSN 08/920,630. Thus, both applications from which priority was claimed were disclosed at the time the present application was filed. Applicants amendment

herein merely clarifies the relationship between the two claimed priority applications by reflecting what is already shown on the face of priority application PCT/US98/17769.

For all these reasons, the amendment to the specification is proper, ripe and does not add new matter. Its entry is respectfully requested.

### **Bases for Rejection**

Claims 59-71 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,258,125 (Paul).

Claims 59-66 and 68-70 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,728,159 (Stroeve).

Claims 59-71 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by WO 98/17209 (Pafford).

The Applicants will address each basis for rejection in Sections I-III, respectively, which follow.

#### **I. Anticipation over U.S. Pat. 6,258,125 (Paul)**

Claims 62-68 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,258,125 (Paul). Claims 62-64 and 67-68, which have written support in the parent application filed 08/27/98, have been cancelled; whereas, claims 65-66, which have written support in the grandparent application filed 08/27/97, remain. Specifically, claim 65, which is directed to “[t]he elongated bone implant of claim 59, wherein said substantially planar upper surface and said substantially planar lower surface, or both are machined to display a ridged surface to aid in preventing said bone implant from moving out of place.” Support for claim 65 is found in the grandparent specification at page 8, lines 23-27 (“ . . . an external feature may be machined into the upper and lower surfaces **to prevent backing out of the implant** upon insertion into the intervertebral space. This may be achieved by a number of means, such as by machining annular rings, indentations and projections, ribbing or teeth into the upper, lower, or both surfaces of the

implant.”) and at page 8, line 29 to page 9, line 1 (Alternately, the implant is passed several times over a **ridged** surface which cuts the desired tooth profile into the upper, lower or both surfaces of the implant.”); emphasis added in bold. Likewise, claim 66, which is directed to “[t]he elongated bone implant of claim 65, wherein said substantially planar upper surface and said substantially planar lower surface are machined to display ridges that are configured **to prevent sliding of said bone implant back** toward the direction from which said bone implant is inserted,” is supported by the disclosure at page 8, lines 23-27 as cited above. Finally, Figs 1C and 1D exemplify such ridges. Thus, claims 65-66 of the present application have written support in the grandparent specification as filed 08/27/97.

Paul, which is relied upon by the Patent Office, has an earliest claimed priority date of 08/03/98. However, when the Applicants’ claim of priority is properly stated, as amended herein, the present invention claims priority back to 08/27/97, based upon the filing date of USSN 08/920,630. Moreover, as argued in Applicants’ Response to the Official Action of 12/05/02 at page 4, the Applicants are claiming embodiments that have written support in Figures 8A-8C of the present application which are also Figures 8A-8C of the grandparent priority application, USSN 08/920,630, filed 08/27/97. Thus, when the Applicants’ claim of priority is properly recited, Paul is not prior art. The withdrawal of this basis for rejection and the allowance of claims 65-66 over Paul are respectfully requested.

## II. Anticipation over U.S. Pat. 5,728,159 (Stroevert)

Claims 59-66 and 68-70 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,728,159 (Stroevert). Claims 62-64 and 66-67 have been cancelled by amendment herein. Accordingly, only claims 59-61, 65-66 and 69-70 remain subject to this basis for rejection.

To be prior art under 35 U.S.C. § 102(b), Stroevert would have to been **published or issued more than a year** prior to the Applicants’ earliest claimed priority

date. But Stroever issued on 03/17/98, which is **less than one year** prior to the filing date of the Applicants' PCT priority application, PCT/US98/17769, which was filed on 08/27/98, and later than the Applicants' earliest claimed priority date of 08/27/97. Because Stroever did not issue at least one year prior to the Applicants' first claimed priority date, Stroever cannot be prior art under 35 U.S.C. § 102(b). Thus, at best, Stroever must rely upon its filing date of 01/02/97 so as to be prior art under 35 U.S.C. § 102(e).

Rejected claims 59-66 and 68-70 are directed to an "elongated bone implant" wherein the term "elongated" is used as an adjective in its ordinary sense to refer to an implant that is "**slender**," or that is "**long in proportion to width**":

**elongate or elongated** *adj* 1: stretched out : lengthened 2: **long in proportion to width** : **SLENDER**

[Exhibit D: Webster's Ninth New Collegiate Dictionary, Mirriam-Webster Inc., Pub., Springfield MA, 1988 at page 404; emphasis added in bold.]

Thus, when given its ordinary meaning, the word "elongated" means that an object is "**long in proportion to its width**" or that it is **longer than it is wide** so as to be "slender." Accordingly, the Applicants' claims would only read on an object that is "long in proportion to its width," so as to be "slender."

In contrast, the implants of Stroever are not "elongated" as the term is ordinarily used. The Patent Office specifically cites to Figures 1 and 2 of Stroever. [Official Action at page 3.] However, Figures 1 and 2 of Stroever depict an implant that is at least as long as it is wide. Thus, the implants of Figs. 1 and 2 of Stroever are **not elongated** because each is neither "slender" nor "long in proportion to its width." More specifically, the implants of Figs. 2, 3, 6 and 7 of Stroever have lengths and widths that are substantially equidistant, whereas the implants of Figs. 1, 4 and 5 of Stroever have widths that are greater than their length. Consistent with the disclosure that the lengths and widths of the implants of Stroever are substantially equidistant, Stroever refers to the embodiments of his Figures 1-4 as having "diameters", which means that the "cross-

sectional” distances (width and length) are equal or about equal.

The serrated fibular **cross-section** bone grafts shown in **FIG. 1** can have exemplary **diameters** of about 10-14 mm and about 15-18 mm, with exemplary length of 8 mm, 10 mm, 12 mm and 14 mm.

[Stroeve at col. 2, lines 20-21; emphasis added in bold.]

\* \* \*

The serrated humeral **cross-section** bone grafts shown in **FIG. 2** can have exemplary **diameters** within the range of about 19-22 mm, and exemplary lengths of 8 mm, 10 mm, 12 mm and 14 mm.

[Stroeve at col. 2, lines 32-35; emphasis added in bold.]

\* \* \*

The serrated tibial **cross-section** and serrated femoral **cross-section** bone grafts shown respectively in **FIGS. 3 and 4** can have exemplary **diameters** within the range of 23-27 mm, and exemplary lengths of about 10 mm, 12 mm, 14 mm and 16 mm.

[Stroeve at col. 2, lines 45-49; emphasis added in bold.]

Thus, by use of the word “diameter” to describe the implants of Figures 1-4<sup>1</sup>, Stroeve discloses that the implants of his invention have a length and a width in the same cross sectional plane that are equal or about equal.

Moreover, when Stroeve uses the term “length” or “elongate,” he is referring to the vertical length of the implant:

Additionally, **elongate shaft** embodiments can have equivalent diameters, but exemplary **lengths** of 20 mm, 30 mm, 40 mm, 50 mm, 60 mm, 70 mm and 80 mm.

[Stroeve at col. 2, lines 23-26; emphasis added in bold.]

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<sup>1</sup> The implants of Figs 5-7 of Stroeve are “wedges” and thus, do not have parallel opposing faces. See Stroeve at col. 2, line 60.

\* \* \*

According to the present invention, a bone graft section for graft in a patient comprises a body portion cut from **elongate cortical bone**, . . . .

[Stroeve at col. 1, lines 19-21; emphasis added in bold.]

\* \* \*

**Exemplary lengths** of serrated bone graft sections in accordance with the present invention range from about 8 mm to about 80 mm, with exemplary **diameters** ranging from about 10 mm to about 27 mm.

[Stroeve at col. 1, lines 60-63; emphasis added in bold.]

Thus, by use of the term “diameter,” Stroeve discloses bone implants having substantially **equal** distances in going from side to side and from front to back. Moreover, by Stroeve’s above-cited use of the terms “length” and “elongate” in reference to the “**bone**”, Stroeve is ultimately referring to the translation of that length in the “bone” to the vertical height of the implant. Because the bone implants of Stroeve have substantially similar distances in length and width, they are not anticipatory of the “elongated” bone implants of the Applicants’ invention, which by definition require a “slender” body wherein the implant body is “**long [rather than equidistant] in proportion to width.**”

For all these reasons, claims 59-61, 65-66 and 69-70 of the Applicants’ invention would not be anticipated under 35 U.S.C. § 102 for allegedly being anticipated by the equidistant or substantially equidistant cross-sectional **diameters** in the implants of U.S. Pat. 5,728,159 (Stroeve).

### III. Anticipation over WO 98/17209 (Pafford)

Claims 59-71 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by WO 98/17209 (Pafford). Claims 62-64 and 66-67 have been cancelled by amendment herein. Accordingly, only claims 59-61, 65-66 and 69-70 remain subject to

this basis for rejection.

**A. Pafford is not Prior Art**

On its face, Pafford has a publication date of April 30, 1998. In contrast, Pending claims 59-61, 65-66 and 69-71 of the present application are entitled to a priority filing date of 08/27/97. The Patent Office admits that “[t]he priority filing date for applicants’ embodiment shown in figures 8A-8C is 8/27/97” and that “the priority filing date for applicants’ embodiment shown in figures 8D-8F is 8/27/98.” It is respectfully submitted that claims 57-61, 65-66 and 69-71 are supported by the specification filed 08/27/97 and Figures 8A-8C therein. Thus, Pafford would not be prior art to claims 59-61, 65-66 and 69-71 of the Applicants’ invention. At best, Pafford could only be prior art to those elements first disclosed in the specification filed on 08/27/98, such as recited in claims 62-64 and 67-68 (now cancelled). If the Patent Office believes otherwise, it is requested that it specifically point out those elements of claims 59-61, 65-66 and 69-71 not supported by the Applicants’ priority application filed 08/27/07.

**B. Even if Pafford is Prior Art, Pafford is not Anticipatory**

Even assuming for the sake of argument that Pafford is prior art, Pafford would not be anticipatory of any of claims 59-71 of the Applicants’ invention. As discussed in Section II *supra*, each of claims 59-71 is directed to an “elongated bone implant.” While the Patent Office may wish to characterize this as a preambular phrase having no limiting value, independent claim 59 refers back to the “elongated bone implant” of the preamble stating “said implant comprising . . . .” See *Bell Communications v. Vitalink Communications Corp.*, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995) (“These two steps of the claimed method, by referring to “**said** packet,” **expressly incorporates by reference the preamble phrase** “said packet including a source address and a destination address.”); emphasis added in bold. Secondly, the mere fact that the Applicants argued that the phrase “elongated bone implant” is an element of the claims creates an estoppel that bars the

Applicants from later arguing that the phrase “elongated bone implant” is not a limitation. *See Pall Corp v. Micron Separations, Inc.*, 36 USPQ2d 1225, 1230 (Fed. Cir. 1995) (“Prosecution history estoppel limits infringement by otherwise equivalent structures by barring recapture by the patentee of scope that was surrendered in order to obtain allowance of the claims.”) *also Elkay Manufacturing v. Ebco Manufacturing*, 52 USPQ2d 1108, 1112-1113 (Fed. Cir. 1999) (“The prosecution history (or file wrapper) limits the interpretation of claims to exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance.”). Finally, the Federal Circuit has interpreted preambular terms that provide “structure” as a limitation. *See London v. Carson Pirie Scott & Co.*, 20 USPQ2d 1456, 1459 (Fed. Cir. 1991) (“The shank is defined in the preamble as that portion of the hanger ‘between the supporting hook for the hanger and the support for the garment.’ This is not merely a suggested use or ‘clarifying language’ as London argues, but rather a limitation supported by structure which must be satisfied by Samsonite’s clamp, either literally or equivalently, if infringement is to be found.”); *Loctite v. Ultraseal*, 228 USPQ 90, 92 (Fed. Cir. 1985) (“Although it appears in the preamble of the ‘012 claims, the term ‘anaerobic’ breathes life and meaning into the claims and, hence, is a necessary limitation to them.”); *also Diversitech v. Century Steps*, 7 USPQ2d 1315, 1317 (Fed. Cir. 1988) (affirming the District Court’s construction the preambular recitation of “a base for support of equipment. . . . as an essential **limitation** of the claims.”); *see also Corning Glass Works v. Sumitomo*, 9 USPQ2d 1962, 1966 Fed. Cir. 1989) (affirming that the sole preambular recitation of “[a]n optical waveguide” was a limitation to the claims since the claims were directed to those only elements (a) and (b) that also functioned as an optical waveguide.”) Thus, for recitation of structural elements and by reference back, the Applicants’ preambular recitation of “a[n] elongated bone implant for use in spinal fusions,” is an essential element of the claim 59 and the claims that depend thereon.

In contrast, Pafford discloses implants that are either dowels, or that “equidistant” and not “elongated.” Specifically, the Patent Office cites to Pafford at “all figures” and “specifically figures 29-32.” The Patent Office cannot mean “all figures”



since figures 1-8, 24, 43 and 45-52 are directed to dowels which lack a “substantially planar upper surface” and a “substantially planar lower surface” of claim 59, from which all other claims ultimately depend. Similarly, Figures 9, 21, 22, 34 and 37 of Pafford are directed to surgical instruments for the insertion of implants, and thus, could not anticipate an implant. Likewise, Figures 10A, 10B, 11A, 11B, 12-20 and 23 are directed to a combination of a dowel and a surgical instrument for their implantation, and thus, could not anticipate the implant of the Applicants’ invention having a “substantially planar” upper and lower surface. Finally, Figures 26-27, 29-32, 35-36 and 38-42 of Pafford disclose implants that are “equidistant,” *i.e.*, that the distance from anterior end to posterior end (front to back) is equal to the distance from right side to left side, as observed by simple measurement. For these reasons, Figures 1-24, 26-27, and 29-52 would not be anticipatory of claims 59-61, 65-66 and 69-71 of the Applicants’ invention.

Regarding Figures 29-32 of Pafford, the Patent Office contends that an “anterior end” is a “side wall” to attempt to make a case of anticipation:

Pafford teaches a bone implant comprising a substantially planar upper and lower surfaces, an anterior end and a posterior end, a first side wall and a second side wall opposite said first side wall, wherein the first and second side walls extend between the planar surfaces, and wherein the second sidewall comprises a concave surface and the first sidewall comprises a convex surface. **Note the second side wall is interpreted as an interior wall.**

[Official Action at page 4; emphasis in the original.]

In Figures 29-32 of Pafford, Figure 29 depicts the top view of the implant that is the subject of Figures 29-32. As already discussed above, the implant of claims 29 (and thus 30-32) is “equidistant” and not “elongated”. In addition, one skilled in the medical arts recognizes that by definition any human being, or implant inserted into a human being, has an anterior<sup>2</sup> end, a posterior end and two opposing lateral (or side) surfaces. By analogy,

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<sup>2</sup> anterior- in official anatomical nomenclature, used to reference the ventral or belly surface of a body. [Exhibit E: Dorland’s Illustrated Medical Dictionary, 24<sup>th</sup> Edition,

this is the equivalent of the four directions: north, south, east and west. Thus by definition, the “anterior” face of any human or any implant for insertion into a human cannot be both its “anterior” end and its side wall, just as the north pole cannot also be the far east. Accordingly, the obviously curved “anterior” end of the implant of Figures 29-32 of Pafford, which is the only curved surface in the implant of Figures 29-32 of Pafford, cannot be interpreted as also being sidewalls. [See Pafford at col. 10, lines 62-63 (“The spacer 110 includes **anterior** wall 111 . . . [shown as curved]);” emphasis added in bold.]

Finally, the Patent Office cites to Figures 25 and 28 of Pafford for allegedly disclosing an implant “wherein the second side wall comprises a concave surface (right side of figure 25) and the first wall (left side of figure 25) comprises a convex surface.” [Official Action at page 4.] As an initial matter, Pafford describes the implant of Fig. 25 and 28 as a “ring” wherein the “ring” is distinguished from the “chamber” [Pafford at col. 9, line 67 to col. 10, line 1 (“a single ring allograft 50 which provides only a single chamber 55 . . .”)] and the implant of Fig. 28 as a “ring” [Pafford at col. 9, lines 29-32 (“When cortical rings are used as the graft material the ring 50 may be trimmed for a more uniform geometry as shown in FIG 26 or left in place as shown in FIG 28.”)] Thus, Pafford and those skilled in the art would consider the implant of FIG 50 to be a “ring.”

For all these reasons, even if Pafford were prior art (which it is not), Pafford would not anticipate any of claims 59-61, 65-66 and 69-71 of the Applicants’ invention.

## CONCLUSION

Claims 59-71 were finally rejected. Claims 62-64 and 67-68 have been cancelled by amendment herein. Accordingly, only claims 59-61, 65-66 and 69-71 remain pending and subject to rejection.

In view of the amendment clarifying the Applicants’ claim of priority and the evidence and arguments presented herein, Paul and Pafford are no longer prior art against claims 59-61, 65-66 and 69-71. In view of the arguments herein, the rejection of

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W.B. Saunders Company, Philadelphia PA, 1965 at page 101.]

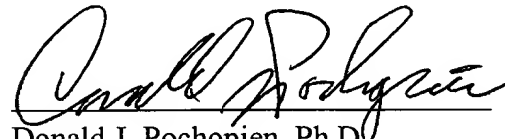
claims 59-61, 65-66 and 69-70 over Stroeve have been rebutted.

Thus, the allowance of claims 59-61, 65-66 and 69-71 is respectfully requested.

Respectfully submitted,

**McANDREWS, HELD & MALLOY, LTD.**

By:



Donald J. Pochopien, Ph.D.

Registration No. 32,167

Attorney for Applicants

500 West Madison Street

Suite 3400

Chicago, Illinois 60661

(312) 775-8133

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